EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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IN RE: BENICAR (OLMESARTAN) PRODUCT LIABILITY LITIGATION	:	Civil No. 15-2606(RBK)(JS)

- - -

February 10, 2017

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PROTECTED INFORMATION

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Oral expert deposition of BENJAMIN LEBWOHL, M.D., M.S., taken pursuant to notice, was held at the law offices of Robins Kaplan LLP, 601 Lexington Avenue, Suite 3400, New York, New York, beginning at 9:45 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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clear that he could continue to list articles that either --
MR. MURPHY: Is that what you're telling him to do?
MR. SLATER: No, I'm not and I can even say it outside -- I just want to make a record that you went to a new subject after you started to question about what articles talk about causation. I just want to make it clear that he wasn't asked are there any more you want to list.
If you want to move to another subject, it's fine. I just don't want the record to seem as if he finished.
MR. MURPHY: Oh, well, I thought you had. I thought that I had the four articles that spoke strongly and then we have Rubio-Tapia --
THE WITNESS: That was not what I meant to convey. I think

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we got --
MR. MURPHY: My apologies. I would like for you to exhaust your list of articles that reached the conclusion that olmesartan causes sprue-like enteropathy.
THE WITNESS: Can you read to me --
MR. MURPHY: Thank you, Adam.
THE WITNESS: Can you read to me the ones that I had mentioned already?
MR. MURPHY: You had Talley, Lebwohl and --
THE WITNESS: Ludvigsson.
MR. MURPHY: -- correct -- Marild and Lagana, Braunstein.
THE WITNESS: I believe I mentioned some others. I mentioned Rubio-Tapia --
BY MR. MURPHY:
Q. Right. I'm saying before we got to Rubio --

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A. I went on and listed Basson at some length, I think --
Q. You listed Basson over here on the right.
A. Why don't I take a look. If you really want every one of them, I must say it's becoming increasingly taken for granted, so it's often listed in the title. Indeed, if you look for the expression "olmesartan-induced enteropathy," that's popping up left and right in PubMed.
Q. Just give me the list of the articles.
A. Why don't I take a look. DeGaetani, did I mention that one yet?
MR. SLATER: Not yet.
THE WITNESS: Would you like me to go to the specific instance of where causation was either explicitly mentioned or at least strongly implied?
MR. MURPHY: I'm just asking

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for the titles of the articles.
THE WITNESS: Okay.
(Pause.)
THE WITNESS: Aziz and colleagues interpret the initial Rubio-Tapia paper as indicating causation.
(Pause.)
THE WITNESS: I would argue that causation is strongly implied in the review article by Nina Burbure and colleagues, B-U-R-B-U-R-E.
BY MR. MURPHY:
Q. And you said, there, it's implied.
A. Strongly implied.
Q. Strongly implied.
A. In the case described by de Fonseka, the title is "A case of olmesartan-induced enteropathy."
I should also point out an item that's in my report, a table of causes of villous atrophy from the

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physician reference uptodate.com, I can reference my report to where that is. That is peer reviewed. It's not in PubMed and it's a subscription service. It's on page 9 of my report. Olmesartan is listed as a cause of small intestinal villous atrophy.

Q. That's not an article, is it? That's just a chart.

MR. SLATER: Up-to-Date?

THE WITNESS: Well, I would point out that it came from an article in Up-to-Date. I did give the caveat that it's not in PubMed. It might not be widely available to the general or scientific public because it is subscription. It's a subscription service that is widely used by physicians, certainly not universally used, but it is a peer-reviewed article.

MR. MURPHY: And that's what I'm trying to understand.

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BY MR. MURPHY:

Q. And the title of the article?

A. I don't have the title of that article.

Q. Okay. All right.

A. On my person.

Q. We can move on.

(Pause.)

THE WITNESS: Marietta, Cartee, Rishi, and Murray, "Drug-induced enteropathy."

Marietta and colleagues, "Immunopathogenesis of olmesartan-associated enteropathy," Alimentary Pharmacology and Therapeutics, 2015. Marthey and colleagues, "Olmesartan-associated enteropathy: results of a national survey," Alimentary Pharmacology and Therapeutics, 2014: "In conclusion, this study shows that olmesartan causes severe and

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potentially life-threatening enteropathy with or without villous atrophy."

Pardon me. Are we limiting this to the peer-reviewed literature or possibly internal Daiichi documents?

MR. MURPHY: Articles. I asked you for the articles.

THE WITNESS: Just making sure.

MR. MURPHY: Okay.

THE WITNESS: Philip and colleagues, "Spectrum of Drug-induced Chronic Diarrhea," Journal of Clinical Gastroenterology.

(Pause.)

THE WITNESS: Uehara and colleagues, "Olmesartan-induced Enteropathy Manifesting as Wernicke-Korsakoff Syndrome."

BY MR. MURPHY:

Q. Before you identify the next

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article, I want to be sure that I remember what you said earlier about Uehara. That was one of the articles of which you had not been aware at the time you generated your report; correct?

A. I believe that either came out later or only made its way to my attention after I finished my report.

Q. Okay. I'm sorry. Go ahead.

A. Theophile and colleagues, "Five cases of sprue-like enteropathy in patients treated by olmesartan."

I should look at my supplementary reliance list to make sure that I'm being complete. I'm not sure if everything in my binder here was on this list, but based on the Uehara article, that suggests that perhaps it is.

Did I mention Philip and colleagues, "Spectrum of Drug-induced Chronic Diarrhea"?

Q. You did.

A. Thank you.

How about Hammoudi and

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

- - -

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION : MDL NO. 2606

- - -

August 23, 2016

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PROTECTED INFORMATION

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Videotape Rule 30(b)(6) deposition of DAIICHI SANKYO, INC., taken through its representative JEFFREY WARMKE, Ph.D., taken pursuant to notice, was held at the law offices of Drinker Biddle & Reath, LLP, 600 Campus Drive, Florham Park, New Jersey, beginning at 9:32 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public for the State of New Jersey.

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protocol did not define asking specific questions about any specific organ class -- organ classes.

Q. The CRFs, the case report forms, do not list anywhere to fill in specific information about any gastrointestinal-related side effects; correct?

A. The case report forms contain a place to report all reported AEs.

Q. There's no place in the case report forms that actually specifically calls out gastrointestinal side effects or related issues. That's not something specifically asked for in the case report form; correct?

A. Correct.

Q. The ROADMAP study was not designed to study gastrointestinal side effects of olmesartan; correct?

A. The primary endpoint of the ROADMAP study was the prevention of microalbuminuria. As part of the study,

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all reported safe -- AEs were collected.

MR. SLATER: Move to strike from "As" forward.

BY MR. SLATER:

Q. The ROADMAP study was not designed to specifically study gastrointestinal side effects of olmesartan; correct?

A. Gastrointestinal events was not one of the prespecified endpoints in ROADMAP.

Q. And it -- gastrointestinal side effects was not the primary endpoint, obviously, and was not a specifically called out secondary endpoint; correct?

A. Gastrointestinal events was not a predefined endpoint in the study.

Q. At any point, did anybody at Daiichi-Sankyo inform Professor Haller or any of the other investigators about postmarketing adverse events that were being received by the company in connection with gastrointestinal side

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effects?

A. No. Professor Haller was clear that he received no communication from Daiichi-Sankyo regarding the potential for gastrointestinal side effects up to and including the time he wrote his letter to the Mayo Clinic.

Q. Did Professor Haller see any patients who had gastrointestinal side effects in his treatment of patients over the years? Did you ask him that when you met with him?

A. I did not ask him that specific question.

Q. Did he tell you anything along that line?

A. He did not volunteer that he had personally witnessed any patients taking olmesartan with gastrointestinal side effects and, in fact, indicated that based on his review of the safety data throughout the course of the ROADMAP study, there was never an issue raised about gastrointestinal side effects by

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the steering committee or by the data safety monitoring committee.

Q. And just to be clear, there was never a time where anyone from Daiichi-Sankyo informed Professor Haller or the other investigators or the steering committee that reports were coming in of gastrointestinal side effects, some being categorized as celiac disease during a period of time; that was not -- that information was not provided to them; correct?

A. As I said before, Professor Haller indicated that he had not received any communications from Daiichi-Sankyo highlighting gastrointestinal side effects.

Q. Would that hold true for the steering committee as well and the other investigators?

A. I did not interview all the steering committee members during my investigation, but Professor Haller indicated that he had not been informed

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I'm not going to go through the whole e-mail, but at the bottom of B, she says, "It is almost impossible to design a late-phase clinical trial with a proper sample size that can detect all real safety signals with conformity as designed, one that can detect the real signal for primary efficacy endpoint with conformity."

Do you see what I just read?

A. Yeah, I see that sentence.

Q. And that's just a statistical analysis of why it would be that you wouldn't look to the data that was supplied by the ROADMAP study to try to determine whether there's an increased risk of cardiac -- cardiovascular mortality because it's just not what was being looked at in this study. Right?

A. I'm going to have to defer that question to the statistical expert.

Q. If you go to the very first e-mail, the first page, there's an e-mail now from Antonia Wang and she points out

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in part, the danger of conducting a small study in this case for cardiovascular event is seen all the time. She speaks through it a little bit more and at the end says, without proper preplanning and appropriate sample size, we can get some results that is inconclusive; correct?

A. Yes.

Q. And certainly there was no effort to establish a sample size large enough to study the question of cardiovascular mortality. That's not what the study was geared for. Right?

A. The ROADMAP study was sized and powered to detect a 30 percent difference in the occurrence of microalbuminuria. It was not powered and sized to detect a meaningful difference in clinical outcomes.

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(Deposition Exhibit No. 3035, 3/4-3/5/10 E-Mail Chain Among Caspard, Cuprys, et al, OLM-DSI-0003999681 and

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OLM-DSI-0003999682, was marked for identification.)

- - -

MR. PARKER: I want to take a break. We've been going for about an hour and 20 minutes.

MR. SLATER: Okay.

MR. PARKER: Okay?

THE VIDEO TECHNICIAN: The time is 2:31 p.m. We are going off the record.

(A recess was taken from 2:31 p.m. to 2:45 p.m.)

- - -

THE VIDEO TECHNICIAN: This is DVD number 4. The time is 2:45 p.m. Back on the record.

BY MR. SLATER:

Q. I've handed you Exhibit 3035, which is some e-mails that address in part the ROADMAP study. Do you see that?

A. Yes, I see the e-mail.

Q. I'm going to just start

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right at the top of the first page, an e-mail from Herve Caspard in pharmacovigilance to Rich Cuprys and Allen Feldman.

Do you see that e-mail at the top?

A. Yes.

Q. Who's Rich Cuprys?

A. Rich Cuprys was in regulatory affairs in the United States.

Q. Herve Caspard writes to him and is talking about a slide presentation and then says towards the bottom that Bill Bailey -- and he's someone in medical affairs; correct?

A. Yes.

Q. -- that Bill Bailey should send me today market research data that will likely be relevant, stressing that the ROADMAP population is very different from the general population treated with olmesartan in the U.S. I would like to consolidate this information in a backup slide.

Do you see that?
A. Yes.
Q. And that's a true statement that the ROADMAP population is very different from the general population treated with olmesartan in the United States; correct?
A. Yeah, there are differences in the inclusion/exclusion criteria used for the study versus what the label indication would be, yes.

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(Deposition Exhibit No. 3036, 6/11/10 E-Mail from DSI Public Affairs to DaiichiSankyo - Development Division and DaiichiSankyo - Employees Only - Commercial, OLM-DSI-0003998943 and OLM-DSI-0003998944, was marked for identification.)

- - -

BY MR. SLATER:
Q. I've handed you Exhibit 3036, and this is a document that was

circulated internally within your company June 11, 2010. Do you see that?
A. Yes.
Q. And it's written -- rephrase.
The document is circulated by DSI public affairs. And DSI, is that Daiichi-Sankyo Japan?
A. No. In the United States, the legal organization for Daiichi is a holding company incorporated in Delaware DSUS, Daiichi-Sankyo U.S. An affiliate of DSUS or a subsidiary company of DSUS is Daiichi-Sankyo, Inc.
Daiichi-Sankyo, Inc. is comprised of the R & D division based in Edison, New Jersey and the commercial division based in Parsippany, New Jersey.
So DSI would be the company that includes the commercial organization and the R & D organization.
Q. This document, Exhibit 3036, is circulated by DSI public affairs and that would be the commercial and R & D,

research and development, arm in the U.S.?
A. Yes, the public affairs division for the U.S. organization.
Q. And this is an internal communication circulated on behalf of Dr. Gormley, who is the president of Daiichi-Sankyo in the U.S.; correct?
A. As noted in the signature line, at this particular time, Dr. Gormley was president of the development division, Daiichi-Sankyo pharma development, which is one of two divisions within DSI.
Q. This is a response to a FDA drug safety communication that was coming out about the ROADMAP study and the ORIENT study; correct?
A. Yes.
Q. And it's pointing out that because the people taking Benicar in these studies had a higher rate of death from cardiovascular causes as compared to placebo, the FDA was looking at data;

correct?
A. That's correct.
Q. In the second to last paragraph from the bottom, the last sentence says, both studies -- which would be ROADMAP and ORIENT; correct?
A. Yes.
Q. -- both studies had included exploratory secondary endpoints, but were not designed to make definitive conclusions beyond the primary endpoints.
And that's a true statement; correct?
A. Yes.

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(Deposition Exhibit No. 3037, 6/16/10 "Olmesartan Cardiovascular Safety" White Paper - FDA Regulatory Response, OLM-DSI-0011644249 through OLM-DSI-0011644324, was marked for identification.)

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BY MR. SLATER:

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Q. That's Exhibit 3037.
Exhibit 3037 is a report titled "White Paper - FDA Regulatory Response" dated June 16, 2010; correct?
A. Yes.
Q. And if I understand correctly, this was a response to the FDA's inquiries about the increased rates of cardiovascular mortality in the ROADMAP and ORIENT studies?
A. Correct.
Q. And this constituted your company's position with regard to those findings and this is what you told the FDA; correct?
A. Yes.
Q. It was signed by Glenn Gormley, the chief scientific officer and president of the company; correct?
A. Yes.
Q. And Kazunori Hirokawa was also a signatory to this report. He's the global head of the research and development unit?

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A. That's correct.
Q. This would be someone who works in Japan?
A. Yes.
Q. If you go to page 10, there's the introduction?
A. Yes.
Q. And if you go -- rephrase.
Please go to page 11, the carry-over page of the introduction, the first -- the second full paragraph. It indicates that it's Daiichi-Sankyo's position that based on the designs, sample sizes, and numbers of incident events in the ROADMAP and ORIENT studies, conclusions about the effects of olmesartan on cardiovascular mortality support a play of chance.
When it says a play of chance, just meaning that they're basically chance findings because of the statistical status of the studies?
A. A chance finding due to the small number of events observed in each study.

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Q. It says: Neither study was designed -- rephrase.
In the second paragraph of the introduction on page 11, the second sentence says: Neither study was designed nor appropriately sized to constitute an adequate test of a safety or efficacy hypothesis related to cardiovascular morbidity or mortality; correct?
A. Yes.
Q. And that's a true statement; correct?
A. Yes.
Q. And that would be a true statement with regard to any of the secondary endpoints; correct?
A. Yes.
Q. This also indicates that there was -- rephrase.
This also indicates that in the ROADMAP study, a large percentage of patients had frank study discontinuations, 1,025 patients, as well

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as protocol-driven discontinuations. Right?
A. Yes.
Q. And thus only 68 percent of randomized patients completed the study while receiving double-blind study medication; correct?
A. Correct.
Q. And these are reasons being stated as to why the cardiovascular mortality figures should not be determinative of the risk/benefit profile. That's what's being advocated here; correct?
A. At the outset, the study was not properly sized for a -- to adequately test those endpoints. Furthermore, the dropouts and discontinuations reduced the available sample size, yes.
Q. At the very end of this section, it says that while Daiichi-Sankyo acknowledges the increase in cardiovascular mortality in these studies, the observations are considered

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to be chance findings that do not warrant any modification to the current olmesartan label.

That's the ultimate conclusion. We don't need to provide any further warnings or information in the label, that's what this says. Right?

A. That is the company's position through this white paper, yes.

Q. If they were -- rephrase. If there was a safety endpoint that was studied and not a chance finding then -- and it did show an increase in a side effect for the olmesartan arm, then it could warrant a modification to the label.

A. You're asking me to answer a hypothetical.

Q. Okay.

Go to page 57, please.

A. (Witness complies.)

Q. This is further analysis of the study and it talks about the ROADMAP study design. Do you see that? 6.1?

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A. Yes.

Q. About five lines down, it says, "This was an event-driven study." What does that mean?

A. This was a prevention study. The event that was driving the study was the occurrence of microalbuminuria.

Q. And then if you go down another few sentences, it says, "ROADMAP was neither designed nor adequately sized as a clinical outcome study."

What does that mean?

A. In this case, the outcome is referring to hard clinical outcomes, like mortality, and so the study wasn't sized to measure differences in mortality between the two treatment groups.

Q. It wasn't sized or designed to study mortality and morbidity or anything other than the primary endpoint; correct?

A. The sample size and the conduct of the trial was designed to answer the question about the first

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incidence of microalbuminuria.

Q. If you could go to page 58, please, the second to the last long paragraph, at the very end of that paragraph, it says: In sum -- the cardiovascular --

A. I'm sorry. Page 58?

Q. I'll start over. If you just go over to page 58 --

A. I've got it. Okay.

Q. -- the next page discussing the ROADMAP study design, it talks about the fact that the double-blind period only had a 68 percent completion rate and there was only a 75 percent completion rate for the overall study; correct?

A. Yes.

Q. And it says, "Thus, information on vital and clinical status at the end of the study is not available for a full 25% of randomized patients."

And that's a true statement. Right?

A. Yes.

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Q. And it says, "This made accurate Kaplan-Meier estimates of cumulative event rates impossible." That's statistical speak, but essentially saying that a certain analysis could not be performed.

A. That is the conclusion that was reached in the white paper, yes.

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(Deposition Exhibit No. 3038, 12/10/09 E-Mail Chain Among Chavanu, Jaffe, et al, OLM-DSI-0008208021 through OLM-DSI-0008208024, was marked for identification.)

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BY MR. SLATER:

Q. I've handed you Exhibit 3038, which is a chain of e-mails in December of 2009 -- December 10, 2009 to be precise -- do you see that?

A. Uh-hum.

Q. If you go to the third page of this e-mail chain, I want to start

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discussions about the contents of the actual article. Right?

A. As we saw earlier, yes, the biostatisticians at Daiichi-Sankyo provided comments to Dr. Haller on the manuscript.

Q. Discussions that Professor Haller did not disclose to you when you met with him and spoke to him for five or six hours. Right?

A. There were discussions that Daiichi-Sankyo provided comments on the manuscript, but it was at the discretion of the steering committee what to accept and what to not accept.

MR. SLATER: Move to strike from "but" forward.

BY MR. SLATER:

Q. When you spoke to Dr. -- Professor Haller for six hours or whatever it was, asked him about this process, he never disclosed to you the things I showed you in those e-mails a few minutes ago, the fact that people at

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the company saw them as negotiating with him and they were pressuring him to try to make changes, he didn't disclose that to you; correct?

A. There were discussions that comments came from Daiichi-Sankyo, but that it was at his discretion and the steering committee's discretion about which comments to accept and which not to accept.

MR. SLATER: Move to strike.

- - -

(Deposition Exhibit No. 3047, 10/13/15 MedWatch Report for Mfr Report# SP-2006-003369, OLM-DSI-0004767148-R through OLM-DSI-0004767153-R, was marked for identification.)

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BY MR. SLATER:

Q. I've just handed you Exhibit 3047. And this is a MedWatch report for a patient who, if you look at the narrative section, box B 5 on the left,

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you'll see was a patient that was actually in the ROADMAP study.

Do you see that?

A. Yes.

Q. And I can tell you, we've confirmed -- and if you want to reconfirm for yourself, you can -- that this person was in the olmesartan arm. You can take my word for it or you can confirm it yourself if you want to.

A. Okay.

Q. Now, this patient, it indicates, was a 56-year-old woman who was hospitalized due to gastroenteritis and hypokalemia.

Do you see that in the narrative section?

A. Where in the narrative section are you looking?

Q. B 5 --

A. B 5, okay.

Q. -- the box that says "Describe Event or Problem"?

A. Uh-hum.

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Q. And then if you turn to the second page, there's a continuation of that section. At the very top, it indicates in part that the patient was in the active trial phase when the serious adverse event occurred.

Do you see that at the very top of the first line?

A. Yes, yes.

Q. The second paragraph indicates that on November 1, 2006, the patient developed gastroenteritis with hypokalemia. The treatment was discontinued on November 6, 2006 and the patient was hospitalized on November 17.

Further down, it indicates the patient was released on November 28, 2006 from the hospital and all symptoms ended on December 1, 2006.

Do you see that?

A. Yes.

Q. Then if you go down to the middle, there's a follow-up note, March 26, 2007. Do you see that, middle of the

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page?
A. Uh-hum.
Q. It indicates:
Gastroenteritis disappeared and reappeared when study drug was reintroduced on the 3rd of December 2006. The patient finally stopped intake of study medication on 24 December 2006; therefore, the investigator assessed a causal relationship as probable.
And he says: The investigator considered hypokalemia as clearly related to dehydration due to gastroenteritis.
Do you see that?
A. Yes.
Q. And then if you go down, there's further follow-up information, July 10, 2009. It says: Serious adverse event term was completed with hypocalcemia unrelated to study medication. The patient was released from hospital on December 5, 2006 and fully recovered on 31 January 2007.

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Study medication was finally discontinued due to adverse events, diarrhea, and vomiting on 30 December 2006.
Do you see that?
A. Yes.
Q. And then if you go to the bottom, there's assessments and it says, at that point causal relationship -- let me withdraw that. Let me move to the other thing I wanted to show you. One second.
All right. Go now to page 3. And there's a follow-up due to a quality control check on August 7, 2009 which indicates, relationship of the event, hospitalization because of gastroenteritis, was corrected to probably.
And -- you see that. Right?
A. Yes.
Q. Let's go to the very -- page 4, the end of all these updates, the last one: Based on follow-up -- final follow-up information received on 21

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October 2009, the reporter's causality assessment remains unchanged as probably related for the event hospitalization because of gastroenteritis.
And then it says further down, the company's causality assessment remains unchanged as related for the event hospitalization because of gastroenteritis.
Do you see that?
A. Yes.
Q. Now, first of all, the coding on this, even though this person was hospitalized because of -- rephrase.
When you look at the coding, it does not indicate diarrhea and vomiting even though that is referenced in the narrative; correct?
MR. PARKER: Objection. Now we're getting beyond the scope of the notice.
MR. SLATER: I don't think we are. We're talking about the data they reported. Now we're

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going into the core data. This is the source documents.
MR. PARKER: I'm not going to argue. I'm just making a statement for the record.
MR. SLATER: All right.
BY MR. SLATER:
Q. You see that this patient had its -- had the study medication discontinued due to adverse events diarrhea and vomiting on 30 December 2006, but diarrhea and vomiting are not coded adverse event terms on the MedWatch form; correct?
A. Correct.
Q. We also know this patient was being given olmesartan and had a successful dechallenge and then a positive rechallenge: When the person went back on the drug, the symptoms came back. That's documented in this form.
So certainly your company had this information available to it; correct?

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MR. PARKER: Objection as to form.
THE WITNESS: The information is contained on the MedWatch form, yes.
BY MR. SLATER:
Q. Okay.
So your company knew that a patient that was actually being given olmesartan during the ROADMAP study developed gastroenteritis, vomiting, and diarrhea so severe that she was hospitalized. When she went off olmesartan, she got better. When she went back on it, she got sick again.
So your company had firsthand information from a study it was conducting that olmesartan likely caused these symptoms; correct?
MR. PARKER: Objection as to form.
THE WITNESS: The company had the information as reported on the MedWatch form, yes.

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MR. SLATER: You can put that one down. I'm trying to get to the part of the day where we get you home for dinner. Let me just make one note.
(Pause.)
MR. SLATER: Do you watch Fast Times At Ridgemont High?
THE WITNESS: A long time ago.
MR. SLATER: You know when he says, like, this new schedule is so confusing? All this paper is so confusing.
I got a smile out of you. I knew I could get that. Nobody can keep a straight face when you make a Spicolli reference.
- - -
(Deposition Exhibit No. 3048, 5/13/16 MedWatch Report for Mfr Report# DSM-2008-01071, OLM-DSI-0015261736 through OLM-DSI-0015261739, was marked for identification.)
- - -
MR. SLATER: Everybody else? Spicolli fans?
MR. PARKER: I have no idea what you're talking about.
MR. SLATER: That's unfortunate.
MR. PARKER: Okay.
MR. SLATER: We're going to have a screening together, all of us, both firms --
MR. PARKER: Ridgemont High.
MR. SLATER: -- all the firms -- Fast Times At Ridgemont High.
MR. PARKER: Okay.
MR. SLATER: Sean Penn's first major role.
MR. PARKER: He's not one of my favorite actors.
MR. SLATER: You'll like him in this role. It'll loosen you up, Bruce.

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BY MR. SLATER:
Q. Okay. I've handed you Exhibit 3048, which is a MedWatch form for a patient who you can see, if you look in box B 5, was a ROADMAP patient.
Do you see that?
A. B 5, yes.
Q. And I can represent to you that we determined this patient was in the olmesartan arm of the study. You can accept that or, if you need to check it, you certainly can.
A. Okay.
Q. This patient that's described here was a 60-year-old woman who was, according to this, hospitalized due to acute prerenal failure and was in active trial phase when the adverse event occurred. That's what it says on the first page.
Do you see that?
A. Yes.
Q. Go to the second page, please. The second paragraph of the

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exists. Right?
A. No, I do not.
Q. The reason it matters is this -- well, I'll get to it.
Whatever it says in this letter to the editor, I'm not going to walk through the whole letter, he was doing a statistical analysis based on a comparison of the two arms of the study; correct -- well, let me actually ask it differently.
What Professor Haller and Menne did in this letter is, they talked about going back and looking at the data to see if there were intestinal effects in either arm and what was found; correct?
A. He was looking for a difference of incidence of GI AEs between the treatment group and the placebo group.
Q. That was not a subject that was studied, correct, specifically? It wasn't an endpoint at all; correct?

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A. It was not a predefined endpoint.
Q. The study was not powered to evaluate that question. Right?
A. That's correct.
Q. And, in fact, we went through some language in the context of the cardiovascular mortality issue where Glenn Gormley in a white paper and in an internal document actually talked about the fact that you can't draw definitive conclusions about that secondary endpoint because of the way the study was designed. It just -- it's not set up to study that issue.
The same would hold true for gastrointestinal effects probably even to a larger extent. Right?
MR. PARKER: Objection; form.
THE WITNESS: There was not a prespecified endpoint for GI AEs in the study, that's correct.
BY MR. SLATER:

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Q. Nowhere in this letter to the editor to the Mayo Clinic does Dr. Menne or Dr. Haller talk about any of the olmesartan side patients who I showed you today their documentation; that's not discussed here at all. Right?
MR. PARKER: Objection.
MR. SLATER: Let me ask it differently.
BY MR. SLATER:
Q. The specifics of patients who developed or were documented to develop gastrointestinal effects, that's not discussed in detail here. Right?
A. The specifics of patients who developed gastrointestinal AEs in either the olmesartan or the placebo group are not described here.
MR. SLATER: Let's go off the video for a second.
THE VIDEO TECHNICIAN: Sure. The time is 4:31 p.m. Off the record.
- - -

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(A discussion off the record occurred.)
- - -
THE VIDEO TECHNICIAN: The time is 4:41 p.m. Back on the record.
- - -
EXAMINATION
- - -
BY MR. PARKER:
Q. Dr. Warmke, good afternoon. It's now 20 to 5:00. It's been a long day, but I have a few questions I need to ask you to address some of the issues that Mr. Slater reviewed with you today during the course of your deposition. Okay?
A. Okay.
Q. Let's begin where we started today with your qualifications; and I'm not going to repeat anything that's been said, but tell the jury what experience you have professionally with clinical trial.